SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo/E-Amphigen Emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:	
Inactivated Porcine Parvovirus, strain S-80	HI ≥ 94.1*
Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain B-7	RP 1-13.5**
Adjuvant:	
Amphigen Base (liquid paraffin and soy lecithin)***	23,1 mg
Drakeol (liquid paraffin)	64.5 mg
Excipients:	
Thiomersal	0.2 mg

*Geometric mean of the hemagglutination inhibiting antibody titers obtained after the vaccination of rabbits with one dose of a ½ dilution of the vaccine to be tested
**Relative potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs
***Of which 60% (13.875 mg) is liquid paraffin and 40% (9.25 mg) is soy lecithin.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For active immunisation of non-pregnant sows and gilts to reduce the incidence of fever and of sudden death caused by *Erysipelothrix rhusiopathiae* infections (serotypes 1 and 2), to reduce the incidence of the diamond skin lesions caused by *Erysipelothrix rhusiopathiae* infections (serotype 2) and to reduce the transplacental infection and the associated reproductive disorders (reproductive failure due to foetal death, characterized by increased number of mummified foetuses) caused by Porcine Parvovirus (PPV).

Onset of immunity (PPV): Vaccination of breeding sows and gilts before pregnancy according to the schedule described in section 4.9 results in reduction of PPV

transplacental infection during the second third of pregnancy.

Onset of immunity (*E. rhusiopathiae*): from 3 weeks after completion of the primary vaccination.

Duration of immunity (PPV and *E. rhusiopathiae*): 6 months after completion of the primary vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in rectal temperature, around 0.5-1°C was very commonly observed (commonly up to 2.3°C) within the first 4-6 hours after vaccination in the field safety studies. This resolved within 1 day after vaccination.
Anorexia was commonly observed and depression was uncommonly observed after vaccination in the field safety studies. These resolved spontaneously without treatment.

Local reactions in the form of a visible swelling, which may present redness and increased local temperature, of up to a maximum diameter of 6 cm, were very commonly observed in the field safety studies. These reactions lasted for a maximum of 4 days.

Hypersensitivity reactions have been reported very rarely based on post marketing safety experience.

The frequency of possible adverse effects is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

There is no information on the safety of this vaccine during pregnancy in sows. Therefore, the use is not recommended during pregnancy. The vaccine can be used during lactation.

4.8 Interactions with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Intramuscular use, in the neck behind the ear.
Administer one dose of 2 ml in gilts from 5 months of age and in sows, according to the following schedule:

Primary vaccination:

Gilts:
First injection: approximately 6 weeks prior to insemination.
Second injection: approximately 3 weeks prior to insemination.

Sows:
First injection: approximately 3 weeks prior to insemination.
Second injection: approximately 1 day prior to insemination.

Re-vaccination:

One injection approximately 3 weeks prior to subsequent insemination, and no later than 6 months after previous vaccination.

Shake well before administration and intermittently during the process of vaccination. The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions. The vaccine is to be administered aseptically.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a 2-fold vaccine dose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL01

The vaccine contains inactivated Porcine Parvovirus and inactivated *Erysipelothrix rhusiopathiae* (serotype 2). It is intended to stimulate active immunity against Porcine Parvovirus and *Erysipelothrix rhusiopathiae* (serotypes 1 and 2) in gilts and sows.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Components of the adjuvant
Disodium Phosphate
Polysorbate 80
Sorbitan monooleate
Soy lecithin
Liquid paraffin
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Excipients
Thiomersal
Formaldehyde
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene vials of 20 ml (10 doses) and of 50 ml (25 doses), with a Type I chlorobutyl rubber stopper and sealed with an aluminium cap.

Cardboard box of 1 vial of 20 ml (10 doses).

Cardboard box of 1 vial of 50 ml (25 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4205

9. DATE OF FIRST AUTHORISATION

13 December 2016

10. DATE OF REVISION OF THE TEXT

September 2021

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Approved: 30/09/21